JUN 1 8 2010

Exhibit 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K092052

1. Submitter's Identification:

BIONIME CORPORRATION
NO 694, RENHUA ROAD, DALI CITY, TAICHUNG COUNTY, TAIWAN 412
Contact Person: Mr. George Chi
Phone Number: 886-4-24951268
FAX Number: 886-4-24952568

Date Summary Prepared: June 01, 2010

2. Name of the Device: Rightest Blood Glucose Monitoring System, Model GM550

3. Common or Usual Name: Glucose test system
Panel: Clinical Chemistry 75
Product Code: NBW, System, Test, Blood Glucose, Over-the-Counter.
Classification: Class II

4. Device Description:

Our Blood Glucose Monitoring System consists of a Meter, Blood Glucose Test Strips, Two Control Solutions, Lancing Device and lancets.
The Rightest Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Meter, when used with the Rightest Test Strips Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System is verified by the Control Solution.

5. Intended Use:

The Rightest Blood Glucose Monitoring System, Model GM550 is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel in clinical settings or diabetics at home to measure the glucose concentration for aiding diabetes management.

The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, and forearm by using Rightest Blood Glucose Monitoring

System, GM550. This device is not intended for testing neonate blood samples and is not intended for the diagnosis of or screening for diabetes mellitus.

Rightest GS550 Blood Glucose Test Strips are intended for use with the Rightest GM550 Blood Glucose meter in the quantitative measurement of glucose in capillary whole blood from the fingertip, palm, and forearm.

Rightest Control Solutions are intended for use with the Rightest GM550 Blood Glucose meter to check that both the glucose meters and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

6. Predicate Device Information:

The Rightest Blood Glucose Monitoring System GM550 is substantially equivalent to the brand of Rightest Blood Glucose Monitoring System (Alternative Site Testing) noted below.

Name:	Rightest Blood Glucose Monitoring System
Device Company:	Bionime Corporation
510(K) Number:	K042678, K053635 and K062567

7. Comparison to Predicate Devices:

Specification Comparison

Specification	Rightest BGMS GM550 (New Device)	Rightest BGMS GM300 (Predicate Device-K062567)
Interference	Uric acid ≧ 10 mg/dL	Uric acid > 9.0 mg/dL
Memory Capacity	500 blood glucose test results with date and time	300 blood glucose test results with date and time
Power Supply	Two CR2032 batteries	Two 1.5V (AAA) batteries
Power Saving	Turn off automatically 2 minutes after last user action / Press the main button for 4 seconds.	Turn off automatically after 3 minutes no use
Meter Dimension	90.6 mm × 46 mm × 16.5 mm	85.0 mm × 58.0 mm × 22.0 mm
Meter Weight	53.0 ± 5 g with batteries	85.0 g with batteries
Coding	Auto coding	Code key

Minimum Sample Volume	1.0 microliter	1.4 microliter
Test Time	5 seconds	8 seconds
Hematocrit Range	30 - 60%	30 - 55%
LCD display area	47 mm × 33.5 mm	39.0 mm × 38.0 mm
Strip Reagent	1.Glucose Oxidase (GOD) 14.8% 2.Potassium ferricyanide 39.5% 3.Non-reactive ingredients 45.7%	1.Glucose Oxidase (GOD) 8.5% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 43%
Control Solution Reagent (Normal level)	1.Water 84% 2.d-Glucose 0.1% 3.Viscosity enhancing agent 15% 4.Inorganic salts / Buffers 1.0% 5.Dye 0.08% 6.Preservative 0.03%	1.Water 83% 2.d-Glucose 0.1% 3.Viscosity enhancing agent 15% 4.Inorganic salts / Buffers 1.4% 5.Dye 0.005% 6.Preservative 0.03%
Control Solution Reagent (High level)	1.Water 69% 2.d-Glucose 0.3% 3.Viscosity enhancing agent 29.5% 4.Inorganic salts / Buffers 1.0% 5.Dye 0.08% 6.Preservative 0.03%	1.Water 83% 2.d-Glucose 0.3% 3.Viscosity enhancing agent 15% 4.Inorganic salts / Buffers 1.4% 5.Dye 0.005% 6.Preservative 0.03%
Measurement Technology	Oxidase Electrochemical Sensor	
Sample	Capillary whole blood	
Measuring Range	20-600 mg/dL	
Operating Tempature Range	10 ~ 40℃ (50 ~104 ℉)	
Operating Relative Humidity Range	10 ~ 90%	
Battery Life	About 1000 tests	
Monitor	LCD display	

Meter Storage Conditions	-10 ~ 60°C (14 ~140 °F)
Test Strip Storage Conditions	4 ~ 30°C (39 ~86 °F), < 90% relative humidity
The unit of measurement data	Fix on mg/dL

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Blood Glucose Monitoring System.
The evaluation included precision, linearity, interference and hematocrit.

9. Discussion of Clinical Tests Performed:

System Accuracy Study:

For the alternative site:
The accuracy of the alternative site test study of the Rightest™ Blood Glucose Monitoring System was proved by comparing whole blood (plasma equivalent) glucose values on the Rightest™ meter with plasma glucose values on a lab instrument.
A total of 114 patients participated. Each patient collected and tested their own blood samples (from the fingertip, palm and forearm) with the Rightest™ meter. Another blood sample was collected within 5 minutes and got the plasma to be analyzed by the lab instrument. Ninety-seven percent of the test results were within ± 20% of the comparison method results at glucose concentrations ≧75 mg/dL and within ±15 mg/dL at glucose concentrations < 75 mg/dL.
The Results and differences between the two methods, the Rightest Blood Glucose Monitoring System and the Olympus 2700 (Lab instrument used as the reference method) are demonstrated in the tables below.

User Performance Study:

A user performance study was performed to demonstrate that lay consumers could obtain accurate results using the subject device. The study was performed using capillary whole blood from fingertip, palm, forearm, and upper arm sample sites.

Table 1: represents samples for glucose results lower than 75 mg/dL.

Difference range in values between the Olympus value and the Rightest meter value	The percent (and number) of samples for which the difference between the Rightest meter value (Alternative site) and the Olympus value were within the difference range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL	78.9% (15/19)	78.9% (15/19)	42.1% (8/19)
Within ± 10 mg/dL	100% (19/19)	94.7% (18/19)	78.9% (15/19)
Within ± 15 mg/dL	100% (19/19)	100% (19/19)	94.7% (18/19)

Table 2: represents samples for glucose results greater than 75 mg/dL.

Difference range in values between the Olympus value and the Rightest meter value	The percent (and number) of samples for which the difference between the Rightest meter value (Alternative site) and the Olympus value were within the difference range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5%	55.8% (53/95)	55.8% (53/95)	49.5% (47/95)
Within ± 10%	75.8% (72/95)	75.8% (72/95)	71.6% (68/95)
Within ± 15%	91.6% (87/95)	89.5% (85/95)	91.6% (87/95)
Within ± 20%	96.8% (92/95)	96.8% (92/95)	97.9% (93/95)

The "Alternative Site Test" clinical evaluation shows substantial equivalence to Rightest Blood Glucose Monitoring System used in fingertip, palm and forearm position. So the result tells us Rightest blood glucose monitoring system GM550 is suitable to be used in fingertip, palm and forearm.

10. Conclusions:

Results of clinical testing demonstrate that the performance of the Rightest Blood Glucose Monitoring System GM550 testing capillary whole blood is substantial equivalence of Rightest Blood Glucose Monitoring System GM300 (AST). The precision and accuracy of Rightest Blood Glucose Monitoring System GM550 is suitable for its in monitoring the effectiveness of diabetes management at home and in clinical settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 18 2010

Bionime Corporation
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent for
Bionime Corporation
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: k092052
Trade Name: Rightest Blood Glucose Monitoring System, Model GM550
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: June 04, 2010
Received: June 07, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092052

Device Name: **Rightest Blood Glucose Monitoring System, Model GM550**

Indications For Use:

The Rightest Blood Glucose Monitoring System, Model GM550 is intended for the quantitative measurement of glucose in capillary whole blood from the fingertip, palm and forearm by professional healthcare personnel in clinical settings or diabetics at home to measure the glucose concentration for aiding diabetes management.

This device is not intended for testing neonate blood samples and is not intended for the diagnosis of or screening for diabetes mellitus.

Rightest Blood Glucose Test Strips GS550 are intended for use with the Rightest GM550 Blood Glucose meter in the quantitative measurement of glucose in capillary whole blood from the fingertip, palm and forearm.

Rightest Control Solutions are intended for use with the Rightest Blood Glucose Monitoring System, Model GM550 to check that both the glucose meters and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ____X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092052